REMARKS/ARGUMENTS

Claims 11, 12, and 15 are pending in the application. In the Office action dated July 25, 2008, the Examiner rejected all three claims under the written description and enablement requirements of 35 U.S.C. § 112, first paragraph, but indicated that the claims would be allowable if limited to an alcoholic extract of the claimed plant materials. Without conceding the correctness of the rejections, Applicant has amended the claims as suggested; therefore, the claims are now submitted to be in condition for allowance. No new matter has been added.

The Examiner also objected to the substitute specification that was filed on January 3, 2007 as purportedly introducing new matter into the disclosure. Although Applicant disagrees with this characterization, Applicant has submitted a new substitute specification as requested. No new matter has been added. Applicant has updated the specification to include a cross-reference to Applicant's international application (consistent with the Preliinary Amendment filed October 7, 2004), and has made grammatical and idiomatic corrections. In addition, Applicant has addressed the particular points raised on pages 3-4 of the Office action.

Exhibits 1 and 2 to this Amendment provide information regarding the "JD-1(WLD) microporous adsorption resin" referenced in the specification.

As requested, Applicant has submitted a revised declaration of inventorship.

Accordingly, Applicant submits that the application is now in condition for allowance.

Respectfully submitted,
CHRISTIE, PARKER & HALE, LLP

By _____
John D. Carpenter
Reg. No. 34,133
626/795-9900

JDC/jdc

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EXHIBIT 1

Information of type JD-1 (WLD) macroporous adsorption resin

Medicinal New Technology Institute in Medicinal Materials Company of Jianyang City

Chinese Traditional Medicine Research Institute of Sichuan Province

June, 2000

Information of type JD-1 (WLD) macroporous adsorption resin

1. Enterprise standards of type JD-1 (WLD) macroporous adsorption resin

Enterprise Standard

Enterprise standards symbol of type JD-1 (WLD) macroporous adsorption resin: Q/71449991-(B513902209-1999), see Appendix 1.

2. Specification standards of type JD-1 (WLD) macroporous adsorption resin

Name: macroporous adsorption resin

type: JD-1 (WLD)

Structure: styrene type copolymer

Crosslinker: divinylbenzene(DVB)

Porogen: toluene

Appearance: milky white or light yellow beads

Odor: No smell

Polarity: non-polar

Physical parameters:

Water content (%)	≤ 70
Particle size (0.23 ~ 1.25mm) (%)	≥ 95
Bulk Density (dry) (g/ml)	0.23 ~ 0.32
wet superficial density (g/ml)	0.62 ~ 0.68
Skeleton density (g/ml)	1.00 ~ 1.20
Specific surface area (m2/g)	350 ~ 450
Average pore size (nm)	35 ~ 65
Porosity (%)	60.0 ~ 68.0
Volume (ml/g)	1.70 ~ 2.20

Residue of limits resin

Turbidity test

After adding equivalent distilled water, the lixivium of adsorption resin with 3 times amount of ethanol is not turbid.

Toluene, xylene	<50PPM
Diethylene benzene and diethyl benzenes	<40PPM
Alkane	<1PPM
Benzene	<1PPM
Styrene	<1PPM
Phenol	<1PPM
Acrylonitrile	<1PPM
Adsorption saturation	⩾ 40(mg/g)

Use

This product is mainly used to adsorb saponins, alkaloids, flavonoids and other active substances in extract from single medicine or combination of Chinese Traditional Medicine, furthermore, it can reach the purposes, i.e., to enrich active ingredients of Chinese Traditional Medicine, to reduce the dose of Chinese Traditional Medicine.

3. Introduction of macroporous adsorption resin

Type JD-1 (WLD) macroporous adsorption resin for isolation and purification of Chinese Traditional Medicine extract is successfully developed as a new technology product by Medicinal New Technology Institute in Medicinal Materials Company of Jianyang City and Chinese Traditional Medicine Research Institute of Sichuan Province after a long-term cooperation. It belongs styrene-type macroporous adsorbent.

Physical and Chemical Properties

Because of its larger pore size and larger pore volume, high strength skeleton, low broken rate, long life, renewable, high-purity and other special physical properties, therefore, the resin is capable of isolation and purification for various active ingredients of Chinese traditional medicine (saponins, alkaloids, flavonoids, steroids, etc.). Furthermore, it can remove various inorganic ions and heavy metal in single and compound herbal extract. It is widely used for dsorption and purification extract from single medicine or combination of Chinese Traditional Medicine.

Chemical properties of the resin is stabile, i.e., acid-resistant, base-resistant, indissolvable in water and common organic solvents, and it is in stable condition with general oxidizer, reducing agent heat (<150).

Residue limits

By special preparation and processing, the resin have reached no smell. In the resin, there does not exist unreacted raw material monomer, crosslinker DVB and residual porogen toluene, alkanes, etc. They have been reduced to the content allowed in drugs under the limits.

The parts of standards used by the products, type JD-1 (WLD) macroporous adsorption resin,have been made clear and specific provisions in Q/71449991-5 (B513902209-1999) (see Appendix 1). Products refer to standards GB/T9535-88 and GB/T16038-1995, qualitative and quantitative results by type HP5973 GC / MS instrument: in JD-1 (WLD) resin, absolute contents of benzene, styrene, acrylonitrile and others are all under the instrument sensitivity. In aqueous phase of the resin, there is phenol only $<1.0 \times 10^{-7}$ (g / g). Resin powder is extracted by DMF solvent, and absolute content of alkane in its lixivium $<1.4 \times 10^{-7}$ (g / g), toluene $<2.0 \times 10^{-7}$ (g / g), these compounds are in line with the content of " Pharmacopoeia of People's Republic of China , 1995 edtion, Appendix 2 Ⅷ P, determination method of organic solvent residue" provided allowing existence amount of toluene in drugs, the provisions, that is, toluene residues in drug should be less than 100PPM). Acorrding to food additives and medicines standards, the long-term toxicity test results of rats showed no apparent toxicity by directly gavaging rats 300mg/kg the above-mentioned resin powder for six months. (see Appendix 4) Thus, users of extracting traditional Chinese medicine with JD-1 (WLD) macroporous adsorption resin for isolation and purification, may not necessary to purify the resin, and it can be used directly for loaded column.

Using method

During using this product, firstly, adding the resin into water, wet packing columns in accord with request that rate about height and diameter of resin column $\geqslant$ 4, recoil with water to exclude air bubbles, lead to natural settlement of the resin, retain liquid, then it can carry out adsorption on the column.

Resin regeneration

The resin can be used again by being soaked with generally available 2% NaOH solution for several hours and washed to neutral. When necessary, it can also soak the resin with hydrochloric acid: ethanol (1:20) solution for several hours, then wash it to neutral. Subsequently, you can proceed to the next adsorption.

Service life

Reference value of effective using period about resin is tentatively determined as 200.Users should regularly detect resin adsorption. If the adsorption of renewed resin declines more than 30%, that resin has been aging, and replacement for resin is proposed.

EXHIBIT 2

G32 Q/71449991-5

Enterprise standards of Medicinal New Technology Institute of Medicinal Materials Lim. Co. of Jianyang City,Sichuan Province

Q/71449991-5.1-1999
B513902209-1999

Type JD-1 (WLD) macroporous adsorption resin

Published in 1999-12-12 Implemented from 1999-12-18

Published by Medicinal New Technology Institute in Medicinal Materials Lim. Co. of Jianyang City,Sichuan Province

Enterprise standards of Medicinal New Technology Institute of Medicinal Materials Lim. Co. of Jianyang City,Sichuan Province

Q/71449991-5.1-1999
Replace Q/J EG001-1995

Medicinal New Technology Institute of Medicinal Materials Lim. Co.
Approved in 1999-12-12 Implemented from 1999-12-18

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1. Range

   The standard relate to requirements, test methods, sampling, signs, labels, packaging of type JD-1 (WLD) macroporous adsorption resin. The standard applies to suspension polymerization processes, with divinyl benzene as the main raw material, in the presence of polymerization initiator for type JD-1 (WLD) macroporous adsorption resin. It can apply to purification of single and compound herbal extract and purification of various antibiotics and etc..

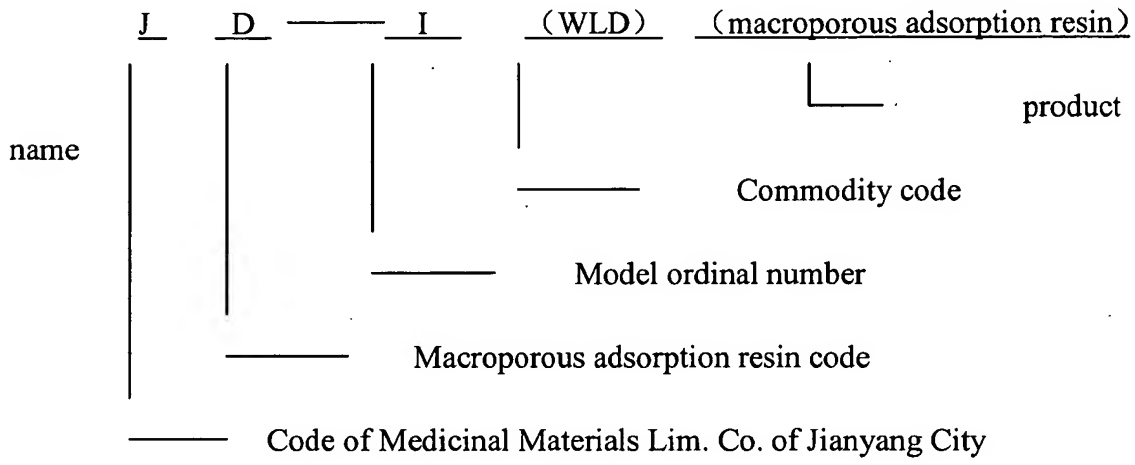
2. Standards cited

The articles required in the following standards, are combined as articles of this standard herein. When the standards are published, following shown editions are all valid. All standards will be amended, and it should explore the possibilities of using the latest version of the following standards during using every aspect of the standards.

GB/T5475-1985 Sampling methods of ion exchange resins
GB/T5476-1996 Preprocessing method of ion exchange resins
GB/T5757-1986 Determination method for water content of ion exchange resins
GB/T5758-1986 Determination method for particle size distribution of ion exchange resins
GB/T8330-1987 Determination method for wet real density of ion exchange resins
GB/T8331-1987 Determination method for wet superficial density of ion exchange resins,

GB/T16867-1997 Determination of residual styrene monomer in the polystyrene and acrylonitrile - butadiene - styrene resin, gas chromatography.
GB/T17323-1998 Standards of bottled purified drinking water
Shanghai Science and Technology Publishing House, in November 1986, the first edition, higher medical institution "Chinese Traditional Medicine pharmacy" textbook (3.4.4), determination method for skeleton density.
People's Health Publishing House, in May 1980, the first edition, textbook of higher medical institution, "Pharmacy" Chapter VIII, detection method for the average pore size and pore volume.

3. Name



4 Request
4.1 Sensory indexes:
Appearance is milky white or light yellow beads.
Odor: No peculiar smell.

4.2 The physical and chemical indicators should be consistent with the provisions in the following table.

Sequence number	Indication name	Index
1	water content (%)	⩽ 70
2	particle size (0.23 ～ 1.25mm) (%)	⩾ 95
3	bulk density (dry) (g / ml)	0.23 ～ 0.32
4	wet superficial density (g / ml)	0.62 ～ 0.68
5	adsorption (g/100g)	4.0 ～ 8.0
6	porogen residues (initial experiment): lixivium of adsorption resin by 3 times volume of ethanol, add equivalent distilled water	not turbid
7	residues of harmful substances	
	Toluene, xylene	<50PPM
	Diethylene benzene and diethyl benzene	<40PPM
	Alkane	<1PPM
	Benzene	<1PPM
	Styrene	<1PPM
	Phenol	<1PPM
	Acrylonitrile	<1PPM
8	skeleton density (g / ml)	1.00 ～ 1.20
9	surface area (m^2 / g)	350 ～ 450
10	average pore size (nm)	40 ～ 100
11	pore volume (ml / g)	1.70 ～ 2.20
12	Porosity (%)	60.0 ～ 68.0

5 Test method

5.1 Sensory inspection

5.1.1 Appearance: visually observe products in transparent area of the test set.

5.1.2 Smell: nasally smell products in the test set.

5.2 Physical and Chemical Indexes

5.2.1 Moisture test

Pre-treatment in accordance with the methods requested in GB/T5476, then determine it in accordance with GB/T5757.

5.2.2 Granularity test

Measure in accordance with the method GB/T5758

5.2.3 Bulk Density test

a) Principle

In a state of absolute dry, the resin weight that the resin contained in unit volume.

b) Standard equipment

constant temperature oven - maximum working temperature is 200 ℃, the maximum temperature error is ± 2 ℃.

Medical balance - sense is 0.1mg.

Graduated cylinder - the smallest scale 0.01ml.

c) Inspection procedures

Preprocessing methods in accordance with the GB5476 after baking with 105 ～ 110 ℃ for 2h, cooling to room temperature, then weigh 3 ～ 5g said resin by scale which a sense is 0.1 mg, and then measuring its size by graduated cylinder which scale is 0.01 ml. Calculating dry bulk density in accordance with following formula. The results of the calculation (bulk density equals to the weight divided by volume)

$D = W / V$ (g / ml)

Wherein:

D - dry resin bulk density (g / ml);

W - dry resin weight (g);

V - the volume of dry resin (ml).

5.2.4, Wet superficial density test

Measurement in accordance with the method GB/T8331.

5.2.5 Adsorbance

By decocting Radix scutellaria, Radix Sophora Flavescens, Radix Hemsleyae and Radix et Rhizome Rhei. Conventionally, there are four solutions of traditional Chinese medicine. Respectively, process the four solutions by saturated adsorption with 100g resin, elution with ethanol, concentration, drying, weighing and calculating, that is.

5.2.6 Porogen residues

The resin products are prepared and dealed with by this special process are detected qualified on the basis of the sixth item of 4.2, and test results according to GB/T16867-1997, i.e., porogen residues $\leqslant$ 1PPM.

5.2.7 Residues of harmful residues and other raw materials monomer

Determined in accordance with GB/T16867-1997.

5.2.8 Skeleton density

According to the Shanghai Science and Technology Publishing House, in November 1986, the first edition, methods in higher medical institution "Chinese Traditional Medicine pharmacy" textbook (3.4.4).

5.2.9 Specific surface area test

a) test principles

Test is in accord with the principles of nitrogen adsorption at low temperature.

b) test equipments

Type digisorb 2600 adsorption instrument -- manufactured by Micrometric company in USA.

c) test procedures

- taking appropriate amount of samples into the sample tube and weighing;
- place the sample tube in the window degassing, degassing in 120 ℃ 10 ~ 4mmHg for 150min;
- after completion of degassing, then weighing the sample tube and calculate the weight of sample after degassing;
- place the sample after degassing in the analysis window, input the data of sample at computer terminals, and add liquid nitrogen into frozen container, then apparatus starts automatically analysis;

- the computer automatically calculates determination results, and a written test reports is given by the typewriter.

5.2.10 Average pore size and pore volume

Detect by the method according to people's Health Publishing House, in May 1980, the first edition, textbook of higher medical institution, "Pharmacy" Chapter VIII.

5.2.11 Porosity

According to: porosity = 1 – (apparent density / skeleton density) in percentage terms

5.2.12 test classification

Tests is classified with Factory inspection and type test.

a) factory inspection

Items of the factory inspection are 1 ～ 6 of items in Table 4.2, each batch test once.

b) type test

One of the following conditions, the type test should be carried out.

- Production of new or old products is changed to another factory, there is trial type identification.
- After formal production, such as structure, materials and technology have greater changes, when it may affect the product performance.
- Resume production of products after long-term stop production.
- Factory test results with the previous test patterns when there are greater differences.
- The annual inspection after normal production.
- State Administration of Quality Supervision requires carry out type test.

Note: The samples of type test are collected in the qualified products, and testing projects according to the requirements of 4.1 ～ 4.2.

6 Sample

6.1 One batch of products is a batch of products with the same raw materials and the same kinds of technology, and the maximum amount does not exceed 2000kg.